FOR OFFICIAL USE ONLY
UNTIL RELEASED BY THE
HOUSE GOVERNMENT REFORM COMMITTEE

WRITTEN TESTIMONY

STATEMENT OF MR. JEAN REED SPECIAL ASSISTANT FOR CHEMICAL AND BIOLOGICAL DEFENSE AND CHEMICAL DEMILITARIZATION PROGRAMS

BEFORE THE COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS, AND INTERNATIONAL RELATIONS

UNITED STATES HOUSE OF REPRESENTATIVES SECOND SESSION 109TH CONGRESS

DOD ANTHRAX DETECTION CAPABILITIES CURRENT AND PLANNED

MAY 9, 2006

FOR OFFICIAL USE ONLY UNTIL RELEASED BY THE HOUSE GOVERNMENT REFORM COMMITTEE Mr. Chairman and distinguished committee members, thank you for the opportunity to appear before you today to discuss the Department of Defense's capabilities regarding detection of anthrax. The Department is a significant stakeholder in this area of concern, and we have committed considerable resources toward mitigation of the effects of anthrax on our Armed Forces.

I am Jean Reed, the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs. In this capacity, I support Dr. Dale Klein, the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs, ATSD(NCB). As Special Assistant to the ATSD(NCB), I have responsibility for oversight of chemical and biological defense programs throughout the Department of Defense.

I have been on the job for about five months. I came to this job from 15 years as a professional staffer for the House Armed Services Committee. In that role, I had an extensive role assisting in the legislative process, notably having the enjoyable task of working to develop the Project BioShield Act of 2004.

In my current position, I find myself on the other side of the table. I am now faced with the challenge of preparing U.S. forces to operate in environments that have been contaminated by chemical and biological agents. U.S. forces are being prepared to operate these types of contaminated environments in support of both homeland defense and homeland security operations.

Today, I will provide a brief status update on DOD biological detection systems that are relevant to the detection of anthrax. I'll begin by laying out for you an overview of the systems that are currently being fielded. Many of these systems are focused on protecting military

personnel in operational environments. However, the technologies used in these systems may have applications to support protection of personnel in buildings.

Fielded Anthrax Detection Equipment

1. Biological Integrated Detection System (BIDS)

BIDS uses a multiple technology approach, both developmental and off-the-shelf materiel, to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully integrated biological detection system. The system is a collectively-protected, High Mobility Multipurpose Wheeled Vehicle (HMMWV)-mounted shelter and is modular to allow component replacement and exploitation of new technologies. The BIDS is a Corps level asset. The current model is capable of detecting and presumptively identifying eight biological warfare (BW) agents simultaneously in 30 minutes. The next generation model is equipped with the Joint Biological Point Detection System, which I will discuss in detail a little further on.

2. Joint Portal Shield (JPS)

JPS is an interim Joint Service biological detection system used to protect high value fixed assets. The system uses an innovative network of sensors to increase probability of detecting a biological warfare attack while decreasing false alarms and consumables. The JPS system consists of a variable number of biological sensors forming a network under the command and control of a centralized command post computer, or CPC. The CPC communicates with and monitors the operation of each sensor. Each sensor is modular in design and can detect and presumptively identify up to ten BW agents simultaneously in less than 25 minutes. In addition, the system has a chemical sensor interface and a radiological sensor interface, which provides an integrated chemical,

biological and radiological sensor network capability. The JPS has been deployed to a total of ten sites in Northeast Asia and 12 sites in the Middle East.

3. Joint Biological Point Detection System (JBPDS)

The JBPDS provides a fully-automated biological point detection capability for the Services throughout the battlespace. The system, which at end state will replace the BIDS and JPS, is more affordable and effective. The sensor suite detects and presumptively identifies ten BW agents simultaneously in less than 20 minutes. The JBPDS is highly maintainable and its modular design is suitable for integration on various platforms and configurations. The system can be operated locally or remotely, and fully automates the functions of: collection, detection, identification, and warning. Its modular design also offers the fastest possible fielding of these systems to meet urgent requirements, as well as the flexibility needed to improve the system continuously with the latest advances in the biological detection, collection, identification, information processing, and engineering sciences.

One modular design variant, referred to as the Homeland Defense Trailer (HDTR), was deployed as part of a network of eight JBPDS systems in the National Capital Region on November 28, 2001, and was fully operational on December 3, 2001. These HDTR systems are deployed in a commercial trailer configuration that was jointly developed and produced.

4. Dry Filter Unit (DFU)

The DFU was developed in response to critical needs identified after the anthrax terrorist attacks in 2001. It is a stand-alone collector that can be used to collect internal and

external ambient air samples for subsequent analysis. It is simple, has an exceptional concentration factor, is inexpensive, and extremely flexible. It is also complementary to and does not replace the role or need for more robust detection systems such as JBPDS, JPS and BIDS.

5. DOD Biological Sampling Kit

The DOD Biological Sampling Kit, with its associated handheld assays, provides a presumptive identification capability for BW agents in environmental samples and are employed for: field screening suspect munitions or munitions fragments for presence of BW agents; screening envelopes or packages that display suspicious liquids, powders or suspensions; screening suspect terrorist laboratory or weapons materials that might be associated with the manufacture or delivery of BW agents; or as a contamination identification kit for indoor areas where it is suspected a BW agent has been released in fairly high concentrations. The DOD Biological Sampling Kit contains a panel of 8 Hand Held Assays, a blue-capped tube containing a bottle of buffer solution and cotton tipped swabs, and a basic instruction card. The DOD Biological Sampling Kit must be stored at 4°C, has a one-time use only capability, and is not for diagnostic use.

The next systems are currently under development, and will significantly improve the Department's anthrax detection capabilities.

Planned Anthrax Detection Capabilities

1. Joint Biological Tactical Detection System (JBTDS)

The JBTDS is being developed to provide the warfighter a lightweight sensor with biological agent detection, warning and sample isolation capabilities. The detector will be networked to provide a cooperative detection capability to increase the probability of warning personnel and reducing the probability of false alarm. JBTDS will be employed remotely or in an unattended configuration, on platforms to include vehicles, aircraft, and by foot-mobile forces.

2. Joint Biological Standoff Detection System (JBSDS)

The JBSDS will use an infrared laser to detect, within 5 kilometers, and discriminate within 1 kilometer, aerosol clouds at operationally significant concentrations. An expedited version is being developed in response to an urgent demand identified by the Joint Chiefs of Staff, and provides 120 degree scanning while operating from fixed sites or mobile platforms in a stationary mode. The next generation system will provide 360 degree scanning while operating on-the-move.

The Department is also developing additional capability within the science and technology sector. First is a technology for an advanced standoff biological detection capability to both detect and discriminate biological aerosol clouds at operationally significant concentrations. Candidate technologies include long-wave and mid-wave infrared (LWIR and MWIR), differential scattering/differential absorption lidar, passive LWIR spectroscopy, and spectral resolution ultraviolet laser induced fluorescence.

In addition to programs under my direct purview, there are several biodetection efforts being developed by the Defense Advanced Research Projects Agency (DARPA). These research efforts are being evaluated for potential application in a variety of roles to support DOD. The Femtosecond Adaptive Spectroscopy Techniques for Remote Agent Detections (FAST-RAD) program, which will demonstrate the capability to detect biological agents at standoff distances. This will be accomplished by performing coherent nonlinear optical spectroscopy, laser pulse shaping techniques, and adaptive optics coupled with strategies that optimize the return signal. By using short pulse lasers with coherence effects, both the spectral and temporal information contained in the backscattered signal will be exploited. This will enable identification of specific agents and provide a mechanism to adapt the system to new agents.

Additionally, DARPA is developing the Handheld Isothermal Silver Standard Sensor (HISSS) and the Spectral Sensing of Bio-Aerosols (SSBA) programs as fieldable systems that will detect biological weapons on the battlefield using hand-held portable detect-to-protect sensors and stand-alone, standoff, detect-to-warn trigger sensors. The SSBA detect-to-warn trigger sensors will be developed for two biosensing areas; the first will be capable of stand-alone detection without consumables, the other will be semi-portable and readily interfaced with the HISSS handheld portable detect-to-protect sensor. The SSBA program addresses the urgent need for biological agent detect-to-warn trigger sensors with fast response times and very low false alarm rates. The goal of this program is to develop point detection sensors with response times of less than one minute and with at least one order of magnitude reduction in false alarm rate relative to currently fielded sensors. The SSBA program will also evaluate whether any of the proposed sensors can provide detection and localization of a biological agent at useful standoff ranges. The HISSS program addresses the urgent need for biological agent detect-to-

protect sensors. They are based on isothermal techniques that replace today's laboratory silver standards such as polymerase chain reaction (PCR), reverse transcriptase PCR, and enzymelinked immunosorbent assay. The goal of the program is to enable battlefield detection for the full biological spectrum of bacteria, viruses, and toxins using a handheld device at or beyond laboratory performance standards.

Now we will shift to a discussion on other biological detection programs within DOD.

Other Biodefense Efforts Within DOD

In the medical field, the Department is fielding the Joint Biological Agent Identification and Diagnostic System, or JBAIDS. JBAIDS is an integrated system for rapid identification and diagnostic confirmation of biological agent exposure or infection. Based on commercial technology, JBAIDS is man-portable, reusable, and capable of the simultaneous identification of multiple biological warfare agents and other pathogens of operational concern. JBAIDS can identify biological agents in a variety of environmental and clinical samples at or below 1,000 colony-forming units or 10,000 plaque-forming units per milliliter. Its detection sensitivity exceeds 85 percent for identification of target agents at specified limit of detection concentrations, and its specificity exceeds 90 percent for identification of target agents at specified limit of detection concentrations.

I would also like to underscore the importance of anthrax detection programs within the Pentagon, such as our new mail screening facility. All mail entering the Pentagon is now screened within bio-safety cabinets in a newly renovated, negatively pressurized facility using extensive HEPA and charcoal filtration. Once mail is screened, samples are sent to an on-site laboratory to test for anthrax and other biological agent using specific DNA and antibody assays. To protect Pentagon employees and the mail screeners, mail is quarantined in an isolation facility

until results come back from the laboratory. Strict procedures ensure mail is not released before test results are returned. In the event of a positive result from the laboratory, mail will continue to be quarantined and proper notifications will be made to the U.S. Postal Service, Department of Homeland Security, Department of Health and Human Services, Environmental Protection Agency, and the White House. Samples will be sent accordingly for confirmatory testing to the U.S. Army Medical Research Institute of Infectious Diseases or another comparable laboratory.

Anthrax Vaccination Immunization Program (AVIP)

Finally, I want to provide you some information regarding the DOD Anthrax Vaccination program. To date, more than five and a half million doses of the vaccine have been administered to over 1.3 million personnel, and over 230,000 have received 6 or more doses.

In December 1997, the Secretary of Defense announced plans to begin vaccinating Service personnel deployed in high-threat areas against the BW agent anthrax. Vaccinations began in March 1998. The AVIP Agency was established in September 1998 to implement and monitor the DOD policy and Services' plans. Due to an unanticipated delay in release of FDA-approved vaccine, DOD slowed its implementation of the AVIP accordingly.

BioPort received approval of their Biologics License Application supplement from the FDA in January 2002, three anthrax vaccine production lots were released, and since then, many more have been released. DOD resumed the AVIP with a priority execution program, continuing with special-mission units, vaccinating forces in high threat areas and expanding vaccinations to early-deploying forces.

In October 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax immunization to protect against inhalation anthrax, pending further Food and Drug Administration (FDA) action.

In January 2005, the FDA granted an Emergency Use Authorization (EUA) for anthrax immunization to prevent inhalation anthrax. In April 2005, the Court modified the injunction to allow anthrax immunization of designated personnel with an option to refuse. The option to refuse required that each service member eligible for immunization be informed that anthrax vaccine was offered under an EUA, provided facts about the vaccine and offered the option to decline immunization without adverse consequences to their military or civilian standing.

In April 2005, the Deputy Secretary of Defense directed the Department to resume anthrax immunizations under the conditions set forth in the EUA. The injunction against mandatory anthrax immunization continued in force. In July 2005, the FDA extended the term of the EUA until January 2006.

In December 2005, the FDA issued a new final order reaffirming its determination that anthrax vaccine is safe and effective for the prevention of anthrax disease, including inhalation anthrax. This action set the stage for further legal proceedings to clarify the legal status of the vaccine and for DOD decisions concerning the future course of the AVIP.

Final Remarks

In conclusion, I want to emphasize the Department's commitment to the development of rapid and effective detection technologies to mitigate the impacts of anthrax attacks upon our servicemen and women, and ensure their safety and well-being. We have many distinct technological challenges; however, we have been successful thus far to bolster our overall efforts in this prominent national security program, and to contribute to national homeland security needs. I welcome your comments on our program's progress, and look forward to working with you to advance our common goal to eliminate the dangers inherent in asymmetrical means of warfare such as chemical and biological weapons.